

§ 20.41

21 CFR Ch. I (4–1–05 Edition)

other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003]

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Freedom of Information Staff pursuant to § 20.40(c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Freedom of Information Staff and is logged in there in accordance with § 20.40(c).

(b) Within 20 working days (excluding Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 20.47, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3)(i) In unusual circumstances, the agency may extend the time for sending the letter for an additional period.

(A) The agency may provide for an extension of up to 10 working days by

providing written notice to the requester setting out the reasons for the extension and the date by which a determination is expected to be sent.

(B) The agency may provide for an extension of more than 10 working days by providing written notice to the requester setting out the reasons for the extension. The notice also will give the requester an opportunity to limit the scope of the request so that it may be processed in a shorter time and/or an opportunity to agree on a timeframe longer than the 10 extra working days for processing the request.

(ii) Unusual circumstances may exist under any of the following conditions:

(A) There is a need to search for and collect the requested records from field facilities or other components that are separate from the agency component responsible for processing the request;

(B) There is a need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(C) There is need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request, or among two or more components of the Food and Drug Administration having substantial subject-matter interest in the determination.

(4) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, Department of Health and Human Services, in accordance with the provisions of 45 CFR 5.34.

(c) The Food and Drug Administration shall provide a determination of whether to provide expedited processing within 10 calendar days of receipt by the Freedom of Information Staff of the request and the required documentation of compelling need in accordance with § 20.44(b).

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990; 59 FR 533, Jan. 5, 1994; 68 FR 25285, May 12, 2003]